INTERNATIONAL STANDARD

IEC 61223-2-10

First edition
1999-09

Evaluation and routine testing in medical imaging departments –

Part 2-10: Constancy tests – X-ray equipment for mammography

Essais d'évaluation et de routine dans les services d'imagerie médicale –

Partie 2-10: Essais de constance – Equipements de mammographie

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For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams*.

* See web site address on title page.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 2-10: Constancy tests – X-ray equipment for mammography

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 61223-2-10 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this standard is based on the following documents:

FDIS	Report on voting
62B/372/FDIS	62B/384/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

Annexes A and F form an integral part of this standard.

Annexes B, C, D and E are for information only.

This standard forms part 2-10 of IEC 61223, which will include the following parts:

Part 1: General aspects

Part 2-1: Constancy tests – Film processors

Part 2-2: Constancy tests – Radiographic cassettes and film changers – Film-screen contact and relative sensitivity of the screen-cassette assembly

Part 2-3: Constancy tests – Darkroom safelight conditions

Part 2-4: Constancy tests – Hard copy cameras

Part 2-5: Constancy tests – Image display devices

Part 2-6: Constancy tests – X-ray equipment for computed tomography

Part 2-7: Constancy tests – Equipment for intra-oral dental radiography excluding dental panoramic equipment

Part 2-9: Constancy tests – Equipment for indirect radioscopy and indirect radiography

Part 2-10: Constancy tests – X-ray equipment for mammography

Part 2-11: Constancy tests – Equipment for general direct radiography

The committee has decided that this publication remains valid until 2003. At this date, in accordance with the committee's decision, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

A bilingual version of this standard may be issued at a later date.

INTRODUCTION

Some provisions or statements in the body of this part of IEC 61223 require additional information. Such information is presented in annex D, Rationale. An asterisk in the left margin of a clause or subclause indicates the presence of such additional information.

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 2-10: Constancy tests – X-ray equipment for mammography

1 Scope and object

1.1 Scope

This part of IEC 61223 applies to those components of X-RAY EQUIPMENT which

– generate, influence the propagation of and detect X-RADIATION;

– process, record and present radiographic information in RADIOLOGICAL INSTALLATIONS with mammographic X-RAY EQUIPMENT using INTENSIFYING SCREENS with RADIOGRAPHIC FILM.

Special accessories of mammographic X-RAY EQUIPMENT such as biopsy plates and stereotactic devices are not within the scope of this standard.

This standard is a part of a series of Particular Publications (international standards and technical reports) which define methods of testing the constancy of operation of various subsystems of diagnostic X-RAY EQUIPMENT.

This standard gives methods of tests for the constancy of properties of diagnostic X-RAY EQUIPMENT as described in IEC 61223-1 (see clause 2).

This part of IEC 61223 is designed to be applicable to X-ray equipment for mammography without digital imaging devices.

1.2 Object

This standard defines

– the essential parameters which describe or affect the performance of the above components of X-RAY EQUIPMENT;

– methods of checking that variations in measured quantities related to those parameters are within acceptable limits, in order to maintain adequate standards of imaging whilst reducing unnecessary IRRADIATION of the PATIENT.

The methods are based upon assessments of RADIOGRAMS of appropriate TEST DEVICES.

The purpose of the methods is

– to establish a reference level of performance when equipment is accepted;

– to detect and verify any significant variation in performance which may require corrective action.

Because RADIOLOGICAL INSTALLATIONS differ widely from each other, it is not possible in this standard to specify target values and tolerances for the parameters which would be generally applicable as criteria of acceptable performance. Guidance is given, however, as to the degree of variation in single measurements which might require appropriate action.

This standard does not deal with

– aspects of mechanical and electrical safety;

– checks of the effectiveness of the direct means of protection against X-RADIATION;

– optimization of imaging performance.

With regard to the measurements, reference is made to methods described in related publications which, for practical reasons, should be carried out prior to the application of the methods described in this standard (see clause 2).

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of IEC 61223. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of IEC 61223 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 60788:1984, *Medical radiology – Terminology*

IEC 61223-1:1993, *Evaluation and routine testing in medical imaging departments – Part 1: General aspects*

IEC 61223-2-1:1993, *Evaluation and routine testing in medical imaging departments – Part 2-1: Constancy tests – Film processors*

IEC 61223-2-2:1993, *Evaluation and routine testing in medical imaging departments – Part 2-2: Constancy tests – Radiographic cassettes and film changers – Film-screen contact and relative sensitivity of the screen-cassette assembly*

IEC 61223-2-3:1993, *Evaluation and routine testing in medical imaging departments – Part 2-3: Constancy tests – Darkroom safelight conditions*

IEC 61223-2-5:1994, *Evaluation and routine testing in medical imaging departments – Part 2-5: Constancy tests – Image display devices*

3 Terminology

3.1 Degree of requirements

In this standard, certain terms (which are not printed in SMALL CAPITALS) have particular meanings, as follows:

– "shall" indicates a requirement that is mandatory for compliance;

– "should" indicates a strong recommendation that is not mandatory for compliance;

– "may" indicates a permitted manner of complying with a requirement or of avoiding the need to comply;

– "specific" is used to indicate definitive information stated in this standard or referenced in other standards, usually concerning particular operating conditions, test arrangements or values connected with compliance;

– "specified" is used to indicate definitive information stated by the MANUFACTURER in ACCOMPANYING DOCUMENTS or in other documentation relating to the equipment under consideration, usually concerning its intended purpose, or the parameters or conditions associated with its use or with testing to determine compliance.

3.2 Use of terms

In this standard, terms printed in SMALL CAPITALS are used as defined in IEC 60788 or other IEC publications or in 3.3 of this standard; see annex A. Where a defined term is used as a qualifier in another defined or undefined term, it is not printed in SMALL CAPITALS, unless the concept thus qualified is defined, or recognized as a "derived term without definition". Test specifications are in italics.

NOTE – Attention is drawn to the fact, that in cases where the concept addressed is not strongly confined to the definition given in one of the publications listed above a corresponding term is printed in lower case letters.

3.3 Definitions

3.3.1
FILM BASE PLUS FOG DENSITY
for CONSTANCY TESTS in X-RAY EQUIPMENT, the optical density in an area of the RADIOGRAM, on the processed control film, that has not been exposed to light from a sensitometer. (This definition has been taken from IEC 61223-2-1.)

3.3.2
NET OPTICAL DENSITY
density above FILM BASE PLUS FOG DENSITY

4 General aspects of CONSTANCY TESTS

For the results of the CONSTANCY TESTS described in this standard to be valid, it is essential to ensure that they are not significantly influenced by anything other than changes in the parameters under test.

In particular, attention shall be paid to darkroom safelight conditions, according to IEC 61223-2-3, and proper film processing, according to IEC 61223-2-1 (see clause 2). When using FILM ILLUMINATORS special attention should also be paid to lighting conditions.

Careful consideration shall be given to the operating and test conditions, under which the equipment is checked, including the influences of environmental changes.

All equipment under test and the test equipment shall be identified at the initial CONSTANCY TEST in order to ensure that the same items are used in subsequent CONSTANCY TESTS.

NOTE – If the MANUFACTURER provides proposals for the method and frequency of CONSTANCY TESTS in the ACCOMPANYING DOCUMENTS, they should preferably be followed.

4.1 General conditions affecting test procedures

The CONSTANCY TESTS described in this standard have been designed to be easily reproducible, i.e., their results should be affected only by changes in the parameters under investigation. The number of test tools and test equipment has been kept to a minimum and restricted where possible to devices that are passive, inherently simple or reasonably stable. However, it is important

– to perform CONSTANCY TESTS with LOADING FACTORS which are the same as those used most frequently in clinical practice;
– to reproduce and record all significant settings of the X-RAY EQUIPMENT and ACCESSORIES each time a test is undertaken, and to check that the same equipment, components and ACCESSORIES are being used;

– to consider the influence of environmental changes on the results. Variations in mains voltage and, if evaluating images from IMAGE DISPLAY DEVICE, room lighting conditions are of special importance;

– to use RADIOGRAPHIC FILM which is handled, processed and viewed in accordance with the standards and technical reports referenced in clause 2;

– to check the performance of the test instrumentation regularly, particularly when any significant variation in the X-RAY EQUIPMENT is suspected.

NOTE – Where appropriate national standards exist, measuring equipment should be referable to them.

Before the CONSTANCY TESTS are started, the constancy of the radiographic film, the film processing and the film viewing conditions have to be checked.

4.2 Establishment of BASELINE VALUES

When new X-RAY EQUIPMENT is brought into use, or any component of the X-RAY EQUIPMENT, ACCESSORIES or test equipment is changed, which may cause a variation in the test result, an initial CONSTANCY TEST shall be carried out immediately after an ACCEPTANCE TEST has indicated that the performance is satisfactory. The purpose of the initial CONSTANCY TEST is to establish new BASELINE VALUES for the parameters tested.

4.3 Frequency of CONSTANCY TESTS

The CONSTANCY TESTS shall be repeated as directed in the appropriate subclauses of this standard. In addition, the CONSTANCY TESTS shall be repeated

– whenever malfunction is suspected;

– immediately after the equipment has undergone maintenance that could affect the performance parameter under test;

– to confirm the test results, whenever the results are outside the criteria.

Records of the BASELINE VALUES shall be kept until a new initial CONSTANCY TEST is performed. The results of the CONSTANCY TESTS shall be kept at least two years.

4.4 Identification of equipment, instrumentation and test conditions

All X-RAY EQUIPMENT under test or used for testing shall be unequivocally identified.

Interchangeable components of X-RAY EQUIPMENT such as

– ADDED FILTERS;

– ANODE material;

– BEAM LIMITING DEVICES;

– compression plates, PATIENT SUPPORT or other attenuating material in the RADIATION BEAM;

– ANTI-SCATTER GRID;

– RADIOGRAPHIC FILM type and emulsion number;

– FILM PROCESSOR;

together with items of test instrumentation such as:

– combination of a RADIOGRAPHIC CASSETTE and INTENSIFYING SCREENS;

– TEST DEVICES;

– sensitometer;

– densitometer;

– force balance;

and settings of variables such as

– FOCAL SPOT TO IMAGE RECEPTOR DISTANCE;

– AUTOMATIC CONTROL SYSTEM density control and sensor position;

– LOADING FACTORS;

– magnification position;

– nominal FOCAL SPOT size, if applicable;

shall be marked and/or recorded so that the items and settings used in the initial CONSTANCY TEST can be used with the mammographic X-RAY EQUIPMENT under test.

NOTE 1 – Most of the tests should be performed with the particular RADIOGRAPHIC CASSETTE used for the initial CONSTANCY TEST. This cassette, hereafter referred to as the "test cassette", may be kept exclusively for test procedures or identified among those used regularly in clinical work. Whereas the first is more likely to provide a stable tool for revealing changes in the equipment, the second approach will be more representative of changes of the whole system, including those due to the ageing of the cassette itself.

NOTE 2 – It is essential that any RADIOGRAPHIC FILM used in the test is of the same type as the film used in clinical practice for mammography.

RADIOGRAMS of a TEST DEVICE shall be taken with the test cassette, with the same INTENSIFYING SCREENS and film type. The RADIOGRAPHIC FILM shall be processed under known comparable conditions, and appropriate allowance shall be made for any changes in film batch according to the method specified in IEC 61223-2-1. If the film type and/or associated processing conditions are changed, a new initial CONSTANCY TEST shall be carried out.

TEST DEVICES are described for each of the performance tests described in clause 5 of this standard. In practice, some tests, for example those described in 5.1 through 5.4, may be performed simultaneously by using a composite TEST DEVICE which combines the properties of a number of individual TEST DEVICES. TEST DEVICES are discussed in detail in annex F.

5 Performance tests

5.1 X-RAY EQUIPMENT – Imaging performance

*5.1.1 Image density

5.1.1.1 Summary

A standard TEST DEVICE is exposed under standard conditions and the NET OPTICAL DENSITY of the image is measured at a specific position in the RADIOGRAM. RADIOGRAMS are made under both manual and AUTOMATIC EXPOSURE CONTROL. Evaluation may reveal changes in the performance under AUTOMATIC EXPOSURE CONTROL as well as changes in the RADIATION output, RADIATION QUALITY, ATTENUATION in the RADIATION BEAM and sensitivity of the imaging system.

5.1.1.2 Test equipment

The test cassette shall be used for this test.

An optical densitometer shall be used which reads consistently within ±0,02 over the range from 0 to 3,5.

The reference thickness of the ATTENUATION PHANTOM (40 mm) is used to simulate a PATIENT during the test under manual control. Three different thicknesses (preferably 20 mm, 40 mm, 60 mm) of the ATTENUATION PHANTOM shall be used for the test under AUTOMATIC EXPOSURE CONTROL.

5.1.1.3 Test procedure

Ensure that all interchangeable parts and the geometric arrangement of the X-RAY EQUIPMENT are as in the initial CONSTANCY TEST. Place the loaded test cassette in the RADIOGRAPHIC CASSETTE HOLDER, and the ATTENUATION PHANTOM in the same position as in the initial CONSTANCY TEST, centred from side to side and aligned with the proximal (chest wall) edge of the breast support table.

a) *Testing under manual control*

Make an IRRADIATION with the manual settings of the LOADING FACTORS of the X-RAY EQUIPMENT as used in the initial CONSTANCY TEST. In the case of an initial CONSTANCY TEST, adjust the LOADING FACTORS and repeat if necessary to obtain a NET OPTICAL DENSITY between 1,0 and 1,6; record the LOADING FACTORS for subsequent use.

b) *Testing under AUTOMATIC EXPOSURE CONTROL*

Ensure that the AUTOMATIC EXPOSURE CONTROL sensor is in the position used for the initial CONSTANCY TEST and completely covered by the TEST DEVICE, with X-RAY TUBE VOLTAGE, density control and other relevant settings identical to those used in the initial CONSTANCY TEST. Make RADIOGRAMS of at least three different thicknesses of the ATTENUATION PHANTOM, in steps of not more than 20 mm and including the 40 mm "reference" thickness. Record, if possible, the IRRADIATION TIME or the CURRENT TIME PRODUCT, the ANODE material and the ADDED FILTER after each IRRADIATION.

Process the exposed films in accordance with the procedure referred to in 4.4. Measure on each RADIOGRAM the NET OPTICAL DENSITY at the point defined in the initial CONSTANCY TEST, which was preferably in the mid-line of the film and between 20 mm and 30 mm from the chest wall. This area may be marked by fixing a fibre washer to the ATTENUATION PHANTOM.

5.1.1.4 Data evaluation

Compare the measured values of NET OPTICAL DENSITY in the RADIOGRAMS with the established BASELINE VALUES, after correcting for changes in the film batch or the processing conditions. Compare the corrected optical densities of the RADIOGRAMS obtained for the different thicknesses of the ATTENUATION PHANTOM (with AUTOMATIC EXPOSURE CONTROL) with the respective values obtained during the initial CONSTANCY TEST.

NOTE – If IRRADIATION TIME or CURRENT TIME PRODUCT data are available, compare the IRRADIATION TIME or CURRENT TIME PRODUCT recorded during the test under AUTOMATIC EXPOSURE CONTROL with the values obtained during the initial CONSTANCY TEST.

5.1.1.5 Criteria to be applied

The NET OPTICAL DENSITY should be within ±0,20 of the BASELINE VALUES.

NOTE – A deviation of ±0,20 with regard to the BASELINE VALUES is acceptable if variations in NET OPTICAL DENSITY due to speed variations in film emulsions and film processing are not included. It is nevertheless well recognized that ±0,10 is a common tolerance limit for breast screening services.

Under AUTOMATIC EXPOSURE CONTROL, any variation in NET OPTICAL DENSITY between tests should be in the same direction and closely correlated for all thicknesses of the ATTENUATION PHANTOM. The range of individual BASELINE VALUES for different thicknesses may be greater than ±0,20 of the value for the reference thickness. If the measured optical densities fall within ±0,20 of their BASELINE VALUES but some have increased and others decreased, further investigation is recommended.

NOTE – If a CONSTANCY TEST on IRRADIATION TIME or CURRENT TIME PRODUCT is performed using the 40 mm thickness of the ATTENUATION PHANTOM, these parameters should normally be within ±20 % of the BASELINE VALUE.

5.1.1.6 Action to be taken

If the system fails to meet the criteria, the guidance given in annex C should be followed.

5.1.1.7 Frequency of constancy tests

The CONSTANCY TEST shall be performed at least quarterly. A higher frequency is recommended if there are doubts concerning the reliability of the X-RAY SOURCE ASSEMBLY, the HIGH-VOLTAGE GENERATOR or the AUTOMATIC EXPOSURE CONTROL.

NOTE – If the X-RAY EQUIPMENT is heavily used, particularly for breast screening, a simplified test, using only the standard thickness of the ATTENUATION PHANTOM and the mode (manual or AUTOMATIC EXPOSURE CONTROL) clinically used, should be repeated at least once a week, or, in the case of remote film processing, daily.

5.1.2 Artefacts

5.1.2.1 Summary

This test is intended to reveal artefacts in the imaging system that might reduce the diagnostic quality of the image. Probable sources of artefacts are ANTI-SCATTER GRID failures such as misalignment, decentring, mechanical damage or incorrect movement and uneven ATTENUATION of the RADIATION BEAM by the breast support, compression paddle or ADDED FILTERS.

5.1.2.2 Test equipment

– FILM ILLUMINATOR;

– Magnifying lens with a magnification factor between 5 and 10.

5.1.2.3 Test procedure

Examine the RADIOGRAMS obtained from the test in 5.1.1, together with the corresponding ones obtained in the initial CONSTANCY TEST. Use a FILM ILLUMINATOR and view the RADIOGRAMS

a) *from the distance normally used in clinical practice; and*

b) *with a magnifying lens.*

5.1.2.4 Data evaluation

a) Compare the gross density variation in the RADIOGRAMS with the corresponding RADIOGRAMS from the initial CONSTANCY TEST. Examine the RADIOGRAMS with respect to the occurrence of patterns, stains, dots and other phenomena that are not present in the initial CONSTANCY TEST.

b) If a MOVING GRID is used, inspect the RADIOGRAM and record any appearance of grid lines.

5.1.2.5 Criteria to be applied

Any visible deterioration in the homogeneity of the film density across the RADIOGRAM, the occurrence of any pattern not present before or the more pronounced appearance of grid lines, should lead to further action.

NOTE – Grid lines should not be visible in normal clinical use, and should not be visible if the ATTENUATION PHANTOM has a thickness of 20 mm or greater as in the present test.

5.1.2.6 Action to be taken

If the system fails to meet the criteria, the guidance given in annex C should be followed.

5.1.2.7 Frequency of constancy tests

This test shall be performed with the same frequency as specified in 5.1.1.7.

5.1.3 High-contrast resolution

5.1.3.1 Summary

This test checks the constancy of the spatial resolution of the X-RAY EQUIPMENT by producing a radiographic image of a high-contrast TEST DEVICE associated with an homogeneous SCATTERING PHANTOM.

NOTE 1 – The purpose of this test is to investigate the constancy of the spatial resolution in a simulated clinical configuration. Where there is a choice of FOCAL SPOTS, the large FOCAL SPOT should be used with the TEST DEVICES resting on the breast support table (contact RADIOGRAPHY) and the small FOCAL SPOT should be used with the TEST DEVICES resting on the magnification stand.

NOTE 2 – The high-contrast TEST DEVICE (see figure 2 and annex F) may be modified by replacing the periodic pattern of radio-opaque material with an arrangement of mesh wires according to the alternative high-contrast TEST DEVICE (see figure 3 and annex F). Data evaluation and criteria to be applied should focus on the detection of any visible deterioration in the image of the mesh wires.

5.1.3.2 Test equipment

The following test equipment is required:

– the test cassette;
– a magnifying lens with a magnification factor between 5 and 10;
– the ATTENUATION PHANTOM of reference thickness (40 mm);
– a high-contrast TEST DEVICE containing periodic patterns of radio-opaque materials. (A detailed description of a high-contrast TEST DEVICE is provided in annex F.)

5.1.3.3 Test procedure

If this technique is commonly used in clinical practice, the CONSTANCY TEST shall be carried out with the MOVING GRID in the RADIATION BEAM.

If the test results do not satisfy the criterion in 5.1.3.5 when using a STATIONARY GRID repeat the CONSTANCY TEST with the STATIONARY GRID removed.

NOTE 1 – *If the test suggests the ANTI-SCATTER GRID may be causing the problem, it is advisable to undertake a separate radiograph to demonstrate the condition of the ANTI-SCATTER GRID.*

NOTE 2 – *To avoid damage, do not remove the MOVING GRID when tools are required to do so.*

Place the loaded test cassette in the RADIOGRAPHIC CASSETTE HOLDER. Use the same type of film and the same FOCAL SPOT TO IMAGE RECEPTOR DISTANCE as in the initial CONSTANCY TEST.

Place the ATTENUATION PHANTOM on the breast support, within ±1 mm of its position used in the initial CONSTANCY TEST. Place the high-contrast TEST DEVICE on top of the ATTENUATION PHANTOM in the same orientation and within ±1 mm of its position used in the initial CONSTANCY TEST. The distance between the high-contrast TEST DEVICE and the film shall be within ±2 mm of that used in the initial CONSTANCY TEST.

Make an IRRADIATION with the LOADING FACTORS used for the initial CONSTANCY TEST. Process the exposed film in accordance with the procedure referred to in 4.4.

NOTE 1 – *Because film density affects the evaluation of high-contrast resolution, it is advisable to work at a film density between 1,2 and 1,6 above FILM BASE PLUS FOG DENSITY.*

NOTE 2 – *Perform this test according to current clinical practice:*

– *The time between loading and IRRADIATION should be the same as in clinical practice. If poor resolution is detected, repeat the test with a delay of 10 min to 20 min between loading and IRRADIATION to allow any entrapped air to escape, and compare the results.*
– *Procedures for loading, exposing and unloading the cassette should be the same as in clinical practice.*

Repeat this procedure for all sizes of FOCAL SPOT and ANODE materials.

5.1.3.4 Data evaluation

Examine the radiographic image with the aid of the magnifying lens and record the maximum spatial frequencies visible in directions parallel with, and perpendicular to, the tube axis. These are the cut-off frequencies under the test conditions. Compare the films with the corresponding RADIOGRAMS from the initial CONSTANCY TEST each time this test is performed, to ensure a consistent criterion of visibility. Note that spurious resolution ("aliasing") may occur: modulation of the image first decreases with increasing object frequency then details reappear in the images of higher frequency objects. The cut-off frequency is that of the *first* disappearance of detail.

5.1.3.5 Criteria to be applied

The measured cut-off frequency shall not be reduced by more than one line pair group compared with the cut-off frequency in the initial CONSTANCY TEST.

5.1.3.6 Action to be taken

If the system fails to meet the criterion, the guidance given in annex C should be followed.

5.1.3.7 Frequency of constancy tests

This test shall be performed according to the INSTRUCTIONS FOR USE as provided by the MANUFACTURER. If no such information is provided, the CONSTANCY TESTS shall be performed at intervals of not more than six months.

5.2 RADIATION BEAM – Geometric characteristics

NOTE – Mammographic X-RAY EQUIPMENT is constructed in such a way that the beam geometry is unlikely to change unless the equipment is visibly damaged or deliberately altered. Reconstruction, replacement of components or service activities that might change the geometric characteristics should be verified by an ACCEPTANCE TEST. Whenever malfunction is suspected, or immediately after the equipment has undergone maintenance that could affect geometric characteristics, the following points shall be checked:

– all interchangeable diaphragms are permanently marked with their field size and intended FOCAL SPOT TO IMAGE RECEPTOR DISTANCE;

– the diaphragms fit firmly in a definite position;

– the LIGHT FIELD provides satisfactory illumination of the breast;

– the LIGHT FIELD and the IMAGE RECEPTION AREA are congruent;

– for units with variable FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, the distance is clearly indicated and the adjustment lock is secure.

5.2.1 Summary

This test is intended to reveal changes in the geometry of the part of the field at the chest wall.

5.2.2 Test equipment

A TEST DEVICE bearing test steel balls on its chest wall side is used to test the constancy of the geometry; see the alternative high-contrast TEST DEVICE in annex F.

5.2.3 Test procedure

The test procedure is the same as in 5.1.3 on high-contrast resolution. The RADIOGRAM of this test may be used.

5.2.4 Data evaluation

Count the number of steel balls totally visible in the RADIOGRAM.

5.2.5 Criteria to be applied

At least two of the five balls at each side of the high-contrast TEST DEVICE shall be totally visible in the RADIOGRAM.

5.2.6 Action to be taken

If the system fails to meet the criterion, the guidance given in annex C should be followed.

5.3 COMPRESSION DEVICE

5.3.1 Summary

The condition of the compression paddle is examined visually. The compression force is measured with a force balance.

NOTE – Due to the nature of mammographic examinations, i.e. the application of final compression manually under supervision of the PATIENT's reactions, only the constancy of automatic motorized pre-compression can be tested. The compression force to be investigated during CONSTANCY TESTS should be chosen according to clinical practice. Though a typical value is in the range between 50 N and 200 N, no value will be proposed here. As it is used only for the pre-compression, a fairly low tolerance for the compression of the motorized compression is acceptable.

5.3.2 Test equipment

The following test equipment shall be provided:

– A force balance with overall reproducibility (including stability and display resolution) better than ±5 N over the range between 50 N and 300 N.

– An air- or water-filled bag, 20 mm to 50 mm thick and 100 mm to 150 mm long and wide, or a soft rubber block of similar dimensions.

5.3.3 Test procedure

Inspect the compression plates for cracks, deformation, local weakening, etc.

Place the force balance on the breast support with the bag on its sensitive area. Operate the COMPRESSION DEVICE and record the reading of the balance. If the maximum force is variable and selective, measure both the highest selectable value and the value normally used clinically. If these values are displayed on the X-RAY EQUIPMENT, record them. Check that compression is applied smoothly and symmetrically and that the compression paddle releases correctly.

Warning – Use a compliant device such as a water-filled bag to spread the force over the compression paddle. Small contact areas will damage the paddle. Ensure that the force balance does not damage the breast support table; use a load-spreading plate if necessary.

5.3.4 Data evaluation

Compare the measured compression force with the established BASELINE VALUES, and, if available, with the reading on the built-in measuring device of the X-RAY EQUIPMENT.

NOTE – Compression forces between 50 N and 200 N are usual in normal clinical use. Local or national clinical service standards may suggest an upper limit.

5.3.5 Criteria to be applied

The manually measured compression force should be within ±10 N of the BASELINE VALUES, and, if applicable, within ±10 N of the reading of the built-in device.

For motorized pre-compression (see note in 5.3.1), the measured compression force should be within ±20 % of the BASELINE VALUES.

5.3.6 Action to be taken

Cracked, deformed or weakened compression paddles should be replaced. Jerky movement, asymmetric compression or failure to release smoothly may require attention to the mechanism or control system.

If the system fails to meet the criteria, the guidance given in annex C should be followed.

5.3.7 Frequency of CONSTANCY TESTS

This test shall be repeated according to the INSTRUCTIONS FOR USE as provided by the MANUFACTURER. If no such information is provided, the CONSTANCY TESTS shall be performed at intervals of not more than six months.

For mammographic equipment with a high WORKLOAD weekly tests are recommended.

5.4 Mammographic cassettes and INTENSIFYING SCREENS

5.4.1 Preparatory measures

When examining the devices, instructions given in the ACCOMPANYING DOCUMENTS shall be followed.

Each single INTENSIFYING SCREEN or pair of INTENSIFYING SCREENS shall be given an individual identification such as a number. This identification shall be marked in an unobtrusive position on one INTENSIFYING SCREEN so that it will be recorded on the film.

The identification shall be repeated on the outside of the mammographic cassette.

Each mammographic cassette shall be labelled with

- type of the RADIOGRAPHIC CASSETTE;
- name of the MANUFACTURER of the INTENSIFYING SCREENS contained;
- types of the INTENSIFYING SCREENS contained;
- date of acquisition of the INTENSIFYING SCREENS;
- date of the most recent cleaning of the INTENSIFYING SCREENS.

The general condition of all mammographic cassettes and the INTENSIFYING SCREENS shall be checked at least every six months as follows:

1) Examine the interior and exterior of each cassette for:
   – correct labelling;
   – signs of warping and fatigue of the material provided to ensure the contact between RADIOGRAPHIC FILM and INTENSIFYING SCREEN.
2) Examine the hinge assembly and closure mechanism of the cassettes for wear and damage.
3) Examine each INTENSIFYING SCREEN and each cassette for dust, dirt, abrasions, worn or stained areas at least monthly. Clean or replace if necessary.

*5.4.2 Contact between INTENSIFYING SCREENS and film

5.4.2.1 Summary

The uniformity and homogeneity of the contact between the INTENSIFYING SCREENS and the film is verified by studying the RADIOGRAM of a wire mesh.

5.4.2.2 Test equipment

Film-screen contact TEST DEVICE

A wire mesh of linear dimensions not less than the IMAGE RECEPTION AREA of the mammographic cassette to be tested.

A detailed description of a film-screen contact TEST DEVICE is given in annex F.

5.4.2.3 Test procedure

Place the mammographic cassette to be tested in the RADIATION BEAM on top of the breast support at the largest FOCAL SPOT TO IMAGE RECEPTOR DISTANCE achievable with the X-RAY EQUIPMENT. Place the wire mesh flat on top of the incident face of the mammographic cassette. If necessary, use a "dummy" cassette in the RADIOGRAPHIC CASSETTE HOLDER to allow an IRRADIATION to be made.

Irradiate the mammographic cassette under test using the smallest FOCAL SPOT available and LOADING FACTORS that will produce an optical density on the processed RADIOGRAM of about 2,5 above FILM BASE PLUS FOG DENSITY in the absence of the wire mesh. If necessary, attenuate the X-RAY BEAM sufficiently to achieve the required optical density by supporting an appropriate thickness of the ATTENUATION PHANTOM so that it completely intercepts the X-RAY BEAM.

IRRADIATION in manual mode is preferable, because it assures the desired density value on the film more easily.

NOTE – Perform this test as according to current clinical practice.

– The time between loading and IRRADIATION should be the same as in clinical practice. If poor contact is detected, repeat the test with a delay of 10 min to 20 min between loading and IRRADIATION to allow any entrapped air to escape, and compare the results.

– Procedures for loading, exposing and unloading the cassette should be the same as in clinical practice.

5.4.2.4 Data evaluation

View the RADIOGRAMS on the FILM ILLUMINATOR under the same conditions as used in clinical practice.

Compare the RADIOGRAM with the RADIOGRAM made during initial CONSTANCY TEST.

5.4.2.5 Criteria to be applied

NOTE – If regions of the image of the wire mesh on the RADIOGRAM appear dark or non-uniform, the film-screen contact may be poor and will impair the quality of the recorded diagnostic information.

Visible impairment of the film-screen contact requires corrective action.

For actions to be taken, the following criterion shall be applied:

– the presence of any areas of poor contact.

NOTE – Good film-screen contact is most important near the chest wall edge of the cassette in mammography, whereas in general RADIOGRAPHY the centre of the cassette is considered the most critical area for film-screen contact.

5.4.2.6 Action to be taken

Large patches of poor film-screen contact may be caused by air trapped between screen and film during loading. This should be suspected where cassettes are machine-loaded and used immediately afterwards (as in many breast screening units). To eliminate this cause, make two test IRRADIATIONS. Establish the test configuration, then make one IRRADIATION immediately after loading the cassette in the normal way. Process the film, reload the cassette, and repeat the test IRRADIATION not less than 12 h later. If the same artefacts are visible, suspect wear or damage to the screen-cassette assembly. If they have disappeared, the fault is almost certainly due to air entrapment.

Further guidance is given in annex C.

5.4.2.7 Frequency of constancy tests

The ACCEPTANCE TEST for new, repaired or re-screened cassettes can form the BASELINE VALUES for the constancy series of tests. Subsequent tests should be carried out according to the INSTRUCTIONS FOR USE as provided by the MANUFACTURER. If no such instructions are provided, the CONSTANCY TESTS shall be performed at least annually.

5.4.3 Relative sensitivity of INTENSIFYING SCREEN-cassette imaging systems

5.4.3.1 Summary

The constancy of the relative sensitivities of INTENSIFYING SCREENS-cassette assemblies is determined by comparing the optical densities produced by equally irradiated mammographic cassettes.

INTENSIFYING SCREENS-cassette assemblies showing deviation from the determined mean optical density of more than ±0,2 are regarded as inappropriate for further mammographic work.

The same batch of RADIOGRAPHIC FILM and the same processing conditions shall be used for all mammographic cassettes tested.

5.4.3.2 Test equipment

The following test equipment shall be provided:

– An ATTENUATION PHANTOM of the standard thickness (40 mm) is used to provide a realistic RADIATION QUALITY and dose rate. A detailed description of the ATTENUATION PHANTOM is provided in annex F.

– An optical densitometer which reads consistently within ±0,02 over the range between 0 and 3,5.

5.4.3.3 Test procedure

Place the ATTENUATION PHANTOM on the breast support.

All RADIOGRAPHIC CASSETTES to be tested are loaded with RADIOGRAPHIC FILMS of the same package.

The loaded RADIOGRAPHIC CASSETTE is placed into the cassette holder and irradiated using the AEC mode with LOADING FACTORS so as to produce an optical density between 0,80 and 1,50 in the processed RADIOGRAM. The test is repeated for all cassettes.

All films shall be processed in the same FILM PROCESSOR and fed into the processor in the same position and orientation, to minimize differences due to inhomogeneous conditions within the FILM PROCESSOR.

5.4.3.4 Data evaluation

The optical density is measured for each RADIOGRAM in the mid-line of the film at a specific distance from the chest wall, for example 30 mm.

5.4.3.5 Criteria to be applied

The deviation of optical density from the mean value should be within ±0,20.

5.4.3.6 Action to be taken

Screen-cassette assemblies not complying with the above criterion shall be rejected for further mammographic work.

Further guidance is given in annex C.

5.4.3.7 Frequency of constancy tests

The ACCEPTANCE TEST for new, repaired or re-screened cassettes can form the BASELINE VALUES for the constancy series of tests. Subsequent tests should be carried out according to the INSTRUCTIONS FOR USE as provided by the MANUFACTURER. If no such instructions are provided, the CONSTANCY TESTS shall be performed at least annually.

5.5 Mammographic film

The recommended test for constancy of the performance of the FILM PROCESSOR incorporates those procedures documented in IEC 61223-2-1. FILM BASE PLUS FOG DENSITY, SPEED INDEX and CONTRAST INDEX are monitored to check constancy. Trends in these parameters can be used to diagnose the particular cause of change and initiate corrective action.

The particular demands of mammography and the distinctive features of mammographic film require that some of the test procedures be carried out with special care, and some additional tests are helpful. These complementary aspects are summarized below.

The control film for the sensitometric test shall be of the same type and of the same emulsion number as the film used for mammography in clinical practice.

The step wedge of the sensitometer should provide two levels of exposure and also enable evaluation of the contrast in the toe of the sensitometric curve. It should therefore provide at least two optical densities on the processed control films within the ranges of 0,20 to 0,30 and 0,40 to 0,60 above FILM BASE PLUS FOG DENSITY. The difference between the measured optical densities of these two steps should be within ±0,03 of the BASELINE VALUE if the diagnostic performance of the film is to remain constant.

New film batches shall be tested together with the old ones before they are used for clinical work. If the results indicate that the new batch does not meet the established criteria, reference should first be made to the MANUFACTURER'S specified tolerances for the parameters measured, or to those agreed in the supply contract for the film. Large deviations in speed, contrast and toe sensitivity may be caused by changes in storage conditions or the use of films of widely differing ages. If clinically significant changes or variations outside the MANUFACTURER'S specification cannot be traced to causes under the USER'S control, the film supplier should be involved to ascertain their origin.

6 Statement of compliance

The test report shall be headed:

Test report

on constancy test of X-ray equipment for mammography

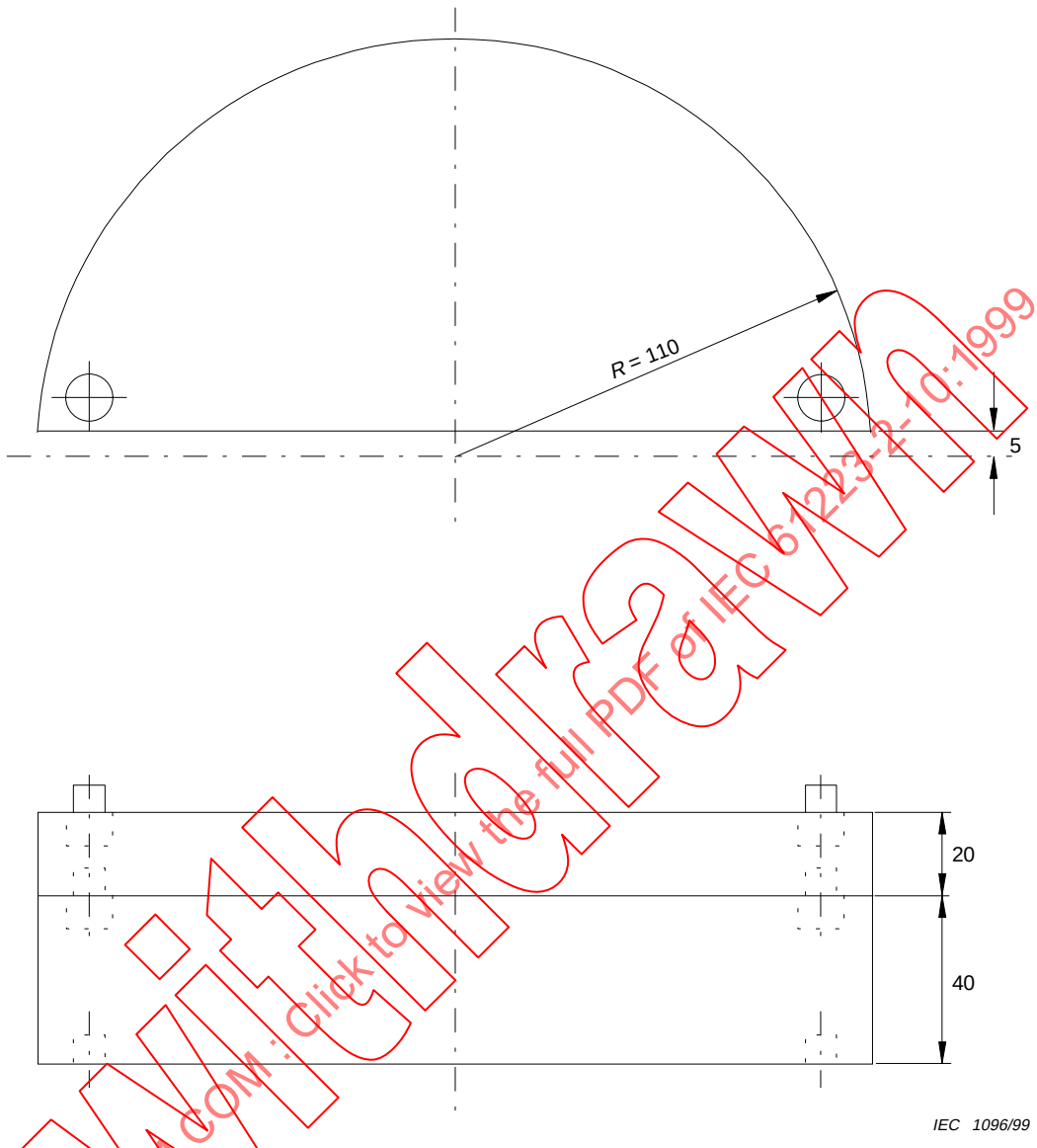
according to IEC 61223-2-10:1999

Compliance with this standard shall be stated as follows:

The X-ray equipment for mammography,....*), complies with IEC 61223-2-10:1999.

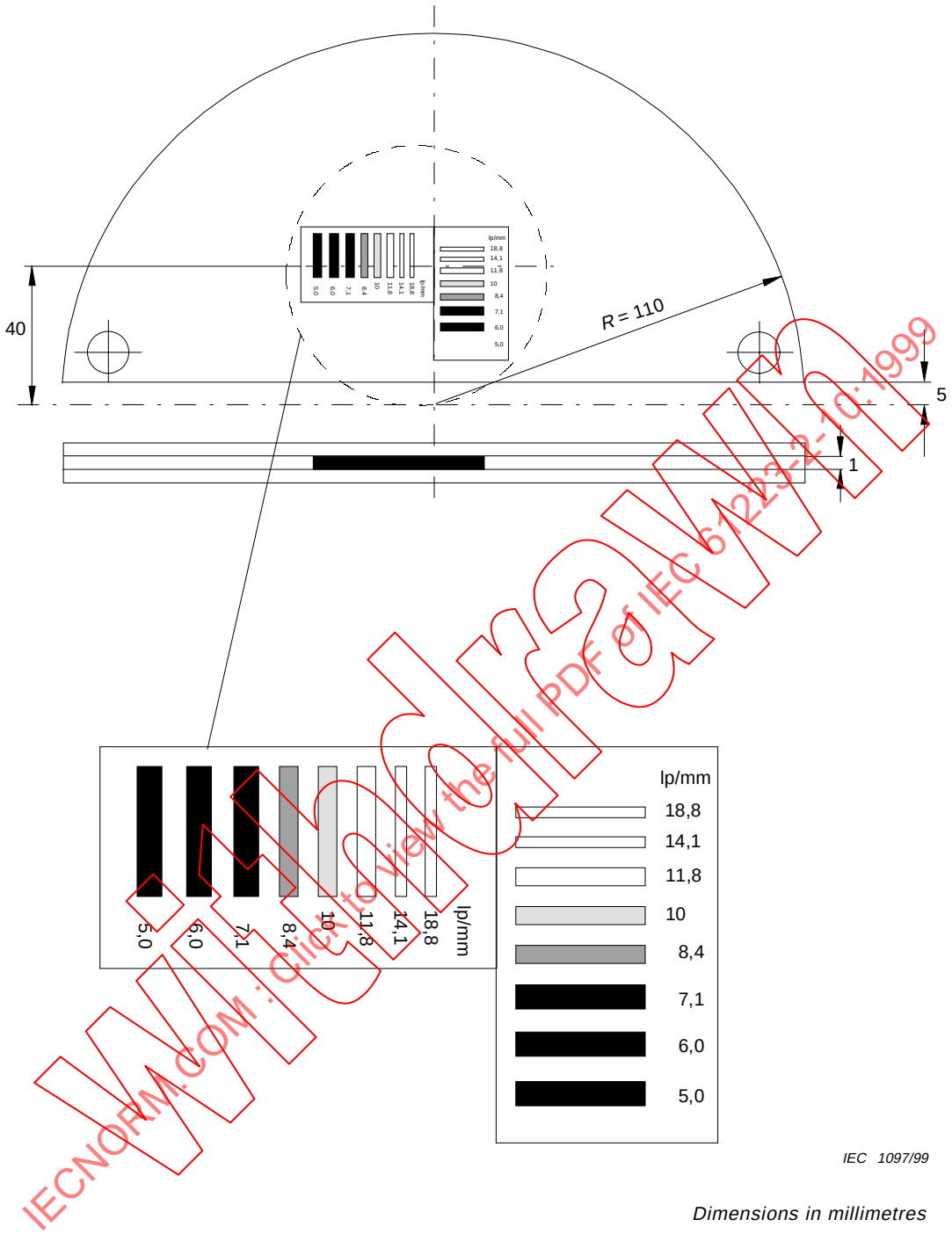
———————

* Identification (for example name of equipment, model or type reference).



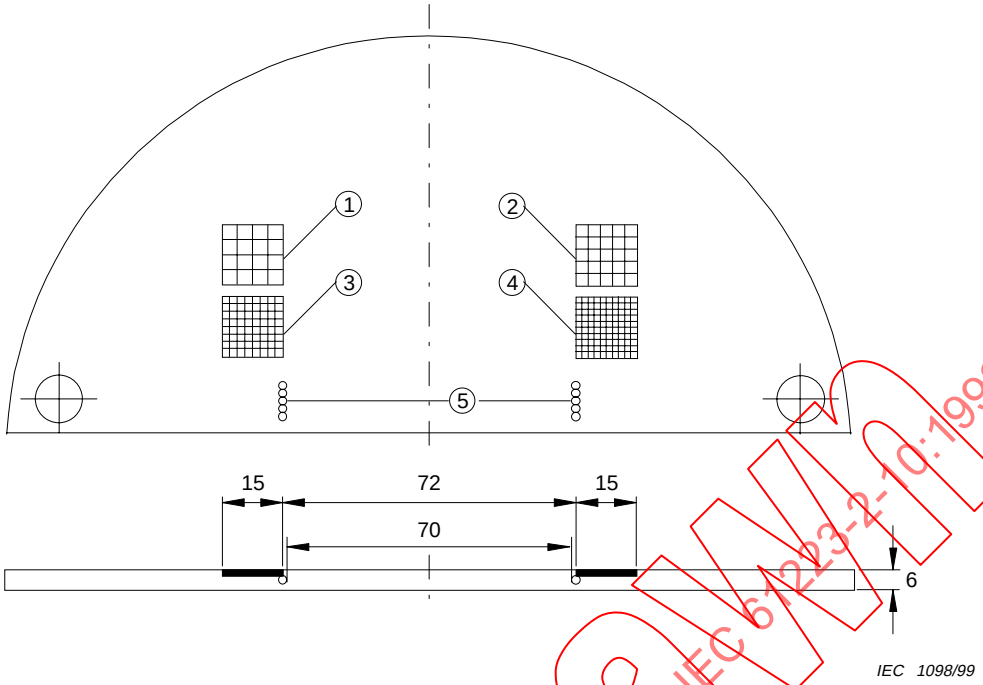
Dimensions in millimetres

Figure 1 – ATTENUATION PHANTOM



Dimensions in millimetres

Figure 2 – High-contrast TEST DEVICE



Key

1 – 4 Stainless steel gauze

1	100 micron	mesh width	60 micron	wire diameter
2	80 micron	"	50 micron	"
3	63 micron	"	40 micron	"
4	40 micron	"	32 micron	"

5 String of balls, of a diameter of 2 mm, to check the position of the radiation beam

Dimensions in millimetres, unless stated otherwise

Figure 3 – Alternative high-contrast TEST DEVICE

Annex A
(normative)

Terminology – Index of defined terms

Annex B
(informative)

Example of a form for the standardized test report

Test report
on constancy tests of X-ray equipment for mammography
according to IEC 61223-2-10:1999

Identifications

Person performing test Identification:

a) X-RAY EQUIPMENT

Mammographic X-RAY EQUIPMENT Identification:

– X-RAY SOURCE ASSEMBLY
– X-RAY TUBE ASSEMBLY
– HIGH-VOLTAGE GENERATOR
– BEAM LIMITING DEVICES

Components and ACCESSORIES Identification:

– ADDED FILTERS
– BEAM LIMITING DEVICES
– PATIENT SUPPORT/RADIOGRAPHIC CASSETTE HOLDER
– compression plates
– ANTI-SCATTER GRID
– RADIOGRAPHIC FILM, Type
– RADIOGRAPHIC FILM, Emulsion number
– RADIOGRAPHIC FILM, Date of first use (batch)
– RADIOGRAPHIC CASSETTE, dedicated for test
– RADIOGRAPHIC CASSETTE, to be tested
– INTENSIFYING SCREENS

Darkrooms Identification:

– FILM PROCESSOR Identification:

NOTE – It may be advisable to record data from the processing of the sensitometric wedge such as temperature of developer, FILM BASE PLUS FOG DENSITY, contrast and speed.

Test equipment Identification:

– ATTENUATION PHANTOM, high-contrast TEST DEVICE, alternative high-contrast TEST DEVICE, film-screen contact TEST DEVICE
– densitometer
– sensitometer
– force balance/scales

Test arrangement Values:

– FOCAL SPOT TO IMAGE RECEPTOR DISTANCE
– reception area
– position and orientation of the TEST DEVICES